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| 09/973,256 | 10/09/2001 | Gyorgy Lajos Kis | OP/4-30969A/N1/CVH21 | 6198 |

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EXAMINER

NICOLAS, FREDERICK C

ART UNIT

PAPER NUMBER

3754

DATE MAILED: 10/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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- atmosphere -

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Office Action Summary

Application No.

09/973,256

Applicant(s)

KIS ET AL.

Examiner

Frederick C. Nicolas

Art Unit

3754

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- ☐ Interview Summary (PTO-413) Paper No(s) _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The preliminary amendment filed 10/9/2001 has been received and entered.
Claims 1-14 have been canceled and new claims 15-24 have been added.

Specification

2. The disclosure is objected to because of the following informalities: line 1 of the abstract, "liquid" should be --liquid--.

Appropriate correction is required.

3. The abstract of the disclosure is objected to because of legal phraseology "said" as recited in lines 2-4,5-7, such terminology should be avoided in the abstract.
Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

I- As to claim 23, there is lack of antecedent basis for the followings: "the physical chemical properties" as recited in line 1; "the requirements" as recited in line 2.

II- As to claim 24, there is lack of antecedent basis for the followings: "the physical chemical properties" as recited in line 1; "the requirements" as recited in line 2.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter (U.S 5,052,558) in view of Czaplinski et al. (U.S 3,709,365).

Carter discloses a package (10) for a pharmaceutical product wherein the package is made of polypropylene (column 2, lines 54-62), autoclaving the package at at least 121°C (column 4, lines 47-68 onto column 5, lines 1-5), after the autoclaving of the package, the package suffers no deformation, does not shrink and does not explode as best seen in Figure 1, a plastic nozzle tip for dispensing the product (see Figure 2 for location), a cap (22) for closing the bottle, wherein the bottle has walls that have a wall-thickness (note: it is inherent the walls of the bottle have a wall-thickness). Carter lacks after autoclaving at at least 121°C and for at least 20 minutes. Czaplinski et al. teaches the use of autoclaving a polypropylene at about 115°-125°C. from 20-30 minutes.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the teaching of Czaplinski et al. into Carter's package as such, in order to treat a material that can withstand autoclaving at a temperature 121°C for at least 20 minutes.

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As to claim 16, lines 1-3, the claimed subject matter "said package meets the requirements of the European Pharmacopoeia, 3rd edition (1997) and the European Union regulation".

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Carter's package as such, in order to comply with the requirements of the European Pharmacopoeia, 3rd edition (1997) and the European Union regulation, as such is notoriously well known in the art.

As to claim 19, the claimed subject matter "the bottle is made of Appryl 3020 SM 3, the nozzle tip is made of Appryl 3020 SM 3, and the cap is made of HDPE GC 7260.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the bottle, the nozzle tip and the cap as such, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

As to claim 21, the claimed subject matter, the bottle has a wall-thickness in the range of 0.3 mm to 0.6 mm, as well as the claimed subject matter in claim 22.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Carter's wall-thickness as such, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. As per MPEP 2144.05

As to claims 23-24, the claimed subject matter, "the physical chemical properties of said polypropylene meet the requirements laid down in the supplement of 1998 of the European Pharmacopoeia, 3rd edition (1997)".

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Carter's package as such, in order to comply with the requirements of the European Pharmacopoeia, 3rd edition (1997), as such is notoriously well known in the art.

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carter (U.S 5,022,558) in view of Czaplinski et al. (U.S 3,709,365) as applied to claim 20 above, and further in view of Ferrari (U.S 4,644,966).

Carter-Czaplinski et al. combination has all the features of the claimed invention except for the bottom portion of the bottle has a concave configuration. Ferrari teaches the use of having a bottle (11) with a concave bottom portion (19).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Carter's bottom portion as such, in order to provide a bottle where any liquid placed on the top surface of the bottom wall will tend to flow in the radially outward directions, as taught by Ferrari.

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carter (U.S 5,022,558) in view of Czaplinski et al. (U.S 3,709,365) as applied to claim 17 above, and further in view of Weiler et al. (U.S 4,178,976).

Carter-Czaplinski et al. combination has all the features of the claimed invention except for the bottle, the nozzle tip and the cap are made of low-density polyethylene.

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Welker, III et al. teaches the use of a low-density polyethylene bottle (column 4, lines 39-64).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the teaching of Weiler et al. into Carter's bottle including the nozzle tip and cap as such, in order to provide a package with a material of construction, which is pharmaceutically acceptable.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. McMillin, Vacek et al., Bayan, Carter, Lockhart, Wolf, Baduel, Schneider et al., Welker, III et al., Bommer, Revenu and Hillerman disclose other types of package for pharmaceutical product.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick C. Nicolas whose telephone number is (703)-305-6385. The examiner can normally be reached on Monday - Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry C. Yuen, can be reached on (703) 308-1946. The fax phone number for the organization where this application or proceeding is assigned is (703)-308-7766.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0861.

FN

October 22, 2002

(Signature) 10/22/02

(Signature)
Henry C. Yuen
Supervisory Patent Examiner
Group 3700